SOPP 8503.2
Review of Import For Export Requests Under Section 801(d)(4) of the FD&C Act

APPENDIX 3

Review Criteria for an IFER and IFERA

Initial Review

An IFER submission should include the following:

- A cover letter, from the U.S. manufacturer, which outlines the Import for Export request and lists the names and addresses of both the foreign material supplier and the U.S. manufacturer. This cover letter should specify the identity of the material to be imported and describe in detail how the imported material will be further processed or incorporated into a product for export only.

- A description of the procedures and safeguards in place to ensure that:
  1) products for export, which incorporate imported components, are not diverted for use in the U.S. (e.g., quarantine procedures for imported blood products and final product for export from U.S. products, including validation data of cleaning procedures used on shared equipment and facilities used for the production of both U.S. products and exported products)**;** and
  2) any products imported for export are segregated from and not co-mingled with products or components intended for use in the U.S.

- A copy of the general donor screening questionnaire used by the foreign supplier to screen donors for high-risk behaviors that could lead to infectious disease transmission. The foreign supplier should not submit the actual questionnaires completed for each donor.

- A copy of a representative product label for the incoming materials. The labels should include the following information (in English):
  - A properly descriptive name.
  - Name(s)and address(es) of establishments collecting, preparing, labeling, or pooling the source material.
  - Donor, lot, or pool numbers.
  - Storage Temperature.
  - Quantity of product.
  - The statement: "Import for Export".
  - The statement: "Not For Use in Products Subject to License Under Section 351 of the Public Health Service Act."
  - The statement: "Caution: For Manufacturing Use Only", or "Caution: For Manufacturing into Noninjectable Products Only".
  - A statement that indicates the product has been tested for infectious disease agents, including, but not limited to: HIV-1, HIV-2, Hepatitis B Virus, Hepatitis C Virus, HTLV-I, HTLV-II, and Syphilis.
  - If the product has tested positive for any of the infectious agents, it must be

appropriately labeled indicating the agent the product is positive for and must also bear the term “Biohazard” prominently in bold letters on the label.

- A certification that tests for infectious disease agents will be performed by the foreign supplier on the blood and blood products. The expected results of these tests should also be included in the submission. The infectious disease agents that should be tested for include, but are not limited to: HIV-1, HIV-2, Hepatitis B Virus, Hepatitis C Virus, HTLV-I, HTLV-II, and Syphilis.

- If the material to be imported for export is expected to test reactive for HBsAg or antibodies to HIV-1, HIV-2, HTLV-I/II, Syphilis, HCV or HbsAg, appropriate circumstances and conditions should exist and suitable procedures should be in place to prevent contagious risks.

- If the foreign supplier performs testing for infectious agents using tests other than those approved by FDA, the submission should include a copy of the labeling (i.e. package insert) for the test kit(s) used, and an English translation of the test kit labeling.

Product Office Reviews

Note: The review is not expected to be as extensive as the review of a typical license application, but is intended to provide the agency with assurance that manufacture of the imported article into an unapproved product for export will not represent a public health risk.

- Determine if adequate cleaning procedures and cleaning validation are in place for any equipment used for the production of both US products, and unapproved products for export, to prevent the cross-contamination between these products.
- Determine if adequate quarantine and separation procedures are in place to prevent release of the imported product and the unapproved product for export into US markets.
- Determine if adequate manufacturing processes and procedures are in place to prevent the commingling of the unapproved product with US approved products manufactured by the firm.
- Evaluate the donor-screening questionnaire used by the foreign supplier to screen donors for high-risk behaviors that could lead to infectious disease transmission.
- Evaluate product labeling of the imported article.
- Determine if the infectious disease testing on the imported product and the results of infectious disease testing on the imported product are appropriate for the proposed use.
- Evaluate any foreign infectious disease testing package inserts submitted for sensitivity and specificity of testing method(s).